

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 02 NOV 2006

WIPO

PCT

Applicant's or agent's file reference B1075.1017	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/09619	International filing date (day/month/year) 29 March 2004 (29.03.2004)	Priority date (day/month/year) 28 March 2003 (28.03.2003)	
International Patent Classification (IPC) or national classification and IPC IPC: A61B 18/18(2006.01) USPC: 606/41			
Applicant C.R.BARD, INC.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>12</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 28 January 2005 (28.01.2005)		Date of completion of this report 07 September 2006 (07.09.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Linda C Dvorak Telephone No. 703 308 0858	

Form PCT/IPEA/409 (cover sheet)(April 2005)

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:
pages 1-111, 13-5 as originally filed/furnished
pages* 12 received by this Authority on 28 January 2005 (28.01.2005)
pages* NONE received by this Authority on _____
- ☒ the claims:
pages NONE as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* 16-24 received by this Authority on 28 January 2005 (28.01.2005)
pages* 25 received by this Authority on 28 January 2005 (28.01.2005)
- ☒ the drawings:
pages 1, 2, 4 as originally filed/furnished
pages* 3 received by this Authority on 28 January 2005 (28.01.2005)
pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/09619**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims <u>5-6,8-25,30-38,43-44,47-48,50-58</u>	YES
	Claims <u>1-4,7,26-29,39-42,45-46,49 and 59-62</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-62</u>	NO
Industrial Applicability (IA)	Claims <u>1-62</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:

Claims 1-4, 7, 26-29, 39-42, 45-46, 49 and 59-62 lack novelty under PCT Article 33(2) as being anticipated by Avitall (5,242,441). The art discloses a method, a catheter with a shaft, an adjustable distal tip, and ring electrodes.

Claims 1-4, 7, 26-29, 39-42, 45-46, 49 and 59-62 lack novelty under PCT Article 33(2) as being anticipated by Hess et al. (4,660,571). The art discloses a method, a catheter with a shaft, an adjustable distal tip, and ring electrodes.

Claims 1-4, 7, 26-29, 39-42, 45-46, 49 and 59-62 lack novelty under PCT Article 33(2) as being anticipated by Webster (6,210,407). The art discloses a method, a catheter with a shaft, an adjustable distal tip, and ring electrodes.

Claims 1-4, 7, 26-29, 39-42, 45-46, 49 and 59-62 lack novelty under PCT Article 33(2) as being anticipated by Mest et al. (6,405,067). The art discloses a method, a catheter with a shaft, an adjustable distal tip, and ring electrodes.

Claims 5, 6, 8-25, 30-38, 43-44, 47-48 and 50-58 lack an inventive step under PCT Article 33(3) as being obvious over Avitall (5,242,441). The claims include obvious design choices/modifications. Simply rearranging or substituting the elements in this context lacks criticality. Further, the specification is silent regarding sufficient criticality or unexpected results as a consequence of the rearrangement.

Claims 5, 6, 8-25, 30-38, 43-44, 47-48 and 50-58 lack an inventive step under PCT Article 33(3) as being obvious over Hess et al. (4,660,571). The claims include obvious design choices/modifications. Simply rearranging or substituting the elements in this context lacks criticality. Further, the specification is silent regarding sufficient criticality or unexpected results as a consequence of the rearrangement.

Supplemental Box

Claims 5, 6, 8-25, 30-38, 43-44, 47-48 and 50-58 lack an inventive step under PCT Article 33(3) as being obvious over Webster (6,210,407). The claims include obvious design choices/modifications. Simply rearranging or substituting the elements in this context lacks criticality. Further, the specification is silent regarding sufficient criticality or unexpected results as a consequence of the rearrangement.

Claims 5, 6, 8-25, 30-38, 43-44, 47-48 and 50-58 lack an inventive step under PCT Article 33(3) as being obvious over Mest et al. (6,405,067). The claims include obvious design choices/modifications. Simply rearranging or substituting the elements in this context lacks criticality. Further, the specification is silent regarding sufficient criticality or unexpected results as a consequence of the rearrangement.

Claims 1-62 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

27 of electrode 21 along portions of the electrode perimeter such that in some orientations, electrode 21 is spaced from tissue surface 25, while in other orientations, shaft 12 is spaced from tissue surface 25.

Referring now to Fig. 9, in another embodiment, electrode 21 may have a flat surface 34 that increases a contact area between electrode 21 and tissue surface 25 when electrode 21 is placed in a certain orientation. As illustrated in Fig. 9, flat surface 34 may be positioned on electrode outer surface 27 such that shaft 12 is at a maximum distance from tissue surface 25 when flat surface 34 is in contact with tissue surface 25. This arrangement may facilitate positioning shaft 12 at a known, pre-determined distance from tissue surface 25. In other embodiments, more than one flat surface may be provided and in still further embodiments the entire electrode outer surface 27 may be formed with flat surfaces. Various flat surfaces may space shaft 12 at different distances from tissue surface 25. In such an embodiment, a measurement of the rotation angle of the electrode can indicate the distance from shaft 12 to tissue surface 25.

Referring now to Fig. 10, one embodiment of an attachment of electrode 21 to shaft 12 and an electrical connection of electrode 21 is illustrated. Lumen 42 extends longitudinally through shaft 12. An electrical lead 48 for providing electrical energy to electrode 21 runs through lumen 42 and passes through a passage 44 in a shaft wall 46 near electrode 21. Electrical lead 48 is soldered, welded, or otherwise electrically connected to electrode 21. If electrode 21 is configured to rotate with shaft 12, electrode 21 may be fixed to shaft 12 with a suitable adhesive or other suitable fixing means. As is known to one skilled in the art, other electrode attachment arrangements are possible.

In embodiments of the present invention that include an electrode that is rotatable relative to shaft 12, an electrical connection between electrical lead and electrode 21 may be accomplished with a brush (not shown) or a biased protrusion (not shown) that remains in contact with an inner surface of a rotating electrode 21.

- 16 -

CLAIMS

1. A catheter for ablating tissue comprising:
a shaft for positioning an ablation ring electrode in contact with or near
a tissue surface; and
5 an ablation ring electrode disposed on the shaft;
wherein the catheter is constructed and arranged to change a distance
between the tissue surface and one of the ablation ring electrode and the shaft near the
ablation ring electrode, without changing a distance between the tissue surface and the
other of the ablation ring electrode and the shaft near the ablation ring electrode.
10
2. The catheter according to claim 1, wherein the ablation ring electrode
is rotatably disposed on the shaft and constructed and arranged to change the distance
between the shaft near the ablation ring electrode and the tissue surface when rotated
around a shaft longitudinal axis.
15
3. The catheter according to claim 1, wherein the ablation ring electrode
is eccentrically shaped.
4. A catheter according to claim 1, wherein the catheter is constructed
20 and arranged to change a distance between the tissue surface and one of the ablation
ring electrode and the shaft near the ablation ring electrode by rotation of the shaft
and/or electrode, or movement of the electrode relative to the shaft.
5. A catheter according to claim 1, wherein the catheter is constructed
25 and arranged to change a distance between the tissue surface and the ablation ring
electrode without changing a distance between the tissue surface and the shaft near
the ablation ring electrode.
6. A catheter according to claim 1, wherein the catheter is constructed
30 and arranged to change a distance between the tissue surface and the shaft near the

AMENDED SHEET

- 17 -

ablation ring electrode without changing a distance between the tissue surface and the ablation ring electrode.

7. A method of adjusting a distance between a tissue surface and one of a shaft and an electrode, comprising:

positioning a catheter shaft at a first distance from a tissue surface, the catheter shaft being near an ablation ring electrode that is mounted on the shaft;

positioning the ablation ring electrode in contact with the tissue surface; and

10 moving the catheter shaft to a second distance from the tissue surface, the second distance being different than the first distance, while maintaining the ablation ring electrode in contact with the tissue surface.

8. The method according to claim 4, comprising rotating the ablation ring electrode relative to the catheter shaft.

9. The method according to claim 5, wherein the ablation ring electrode is mounted eccentrically.

20 10. A method of adjusting a distance between a tissue surface and one of a shaft and an electrode, comprising:

positioning the ablation ring electrode at a first distance from the tissue surface;

25 positioning a catheter shaft at a shaft distance from a tissue surface, the catheter shaft being near an ablation ring electrode that is mounted on the shaft; and

moving the ablation ring electrode to a second distance from the tissue surface, the second distance being different than the first distance, while maintaining the catheter shaft at the shaft distance from the tissue surface.

30

AMENDED SHEET

- 18 -

11. A catheter for ablating tissue, comprising:
a shaft for positioning an ablation electrode in contact with a tissue surface, the shaft having a longitudinal axis; and
an ablation electrode rotatably disposed on the shaft and constructed
5 and arranged to change a distance between the shaft and the tissue surface when rotated around the shaft longitudinal axis.
12. The catheter according to claim 11, wherein the ablation electrode has one continuous outer surface.
- 10 13. The catheter according to claim 11, wherein the ablation electrode is stiff.
14. The catheter according to claim 11, wherein the ablation electrode has
15 an outer surface constructed of a single piece of material.
15. The catheter according to claim 11, wherein the ablation electrode has an outer surface that is oval in a radial cross-section.
- 20 16. The catheter according to claim 11, wherein the ablation electrode has an outer surface that is eccentric in a radial cross-section.
17. The catheter according to claim 11, wherein the ablation electrode has an outer surface that is asymmetric in a radial cross-section.
- 25 18. The catheter according to claim 11, wherein the ablation electrode has an outer surface that is non-circular in a radial cross-section.
19. The catheter according to claim 11, wherein the ablation electrode has
30 a center longitudinal axis and the shaft longitudinal axis is a center longitudinal axis; and

AMENDED SHEET

- 19 -

the ablation electrode is disposed on the shaft such that the ablation electrode center longitudinal axis and the shaft center longitudinal axis are eccentric.

20. The catheter according to claim 11, wherein the ablation electrode is
5 rotatable relative to the shaft.

21. The catheter according to claim 11, wherein the ablation electrode and the shaft are rotatable together.

10 22. The catheter according to claim 11, wherein the shaft is oval in a radial cross-section.

23. The catheter according to claim 11, wherein the shaft is asymmetric in a radial cross-section.

15 24. The catheter according to claim 11, wherein the shaft is eccentric in a radial cross-section.

20 25. The catheter according to claim 11, wherein the shaft is non-circular in a radial cross-section.

26. The catheter according to claim 25, wherein the ablation electrode is circular in radial cross-section.

25 27. The catheter according to claim 25, wherein a width of the ablation electrode is larger than a width of the shaft.

28. The catheter according to claim 17, wherein the shaft is circular in radial cross-section.

30

AMENDED SHEET

- 20 -

29. The catheter according to claim 17, wherein a width of the ablation electrode is larger than a width of the shaft.

5 30. The catheter according to claim 11, wherein the ablation electrode is a ring electrode.

10 31. The catheter according to claim 11', in combination with an ablation energy supply, the energy ablation supply being electrically connected to the ablation electrode.

15 32. A catheter for ablating tissue, comprising:
a shaft having a longitudinal axis;
an ablation electrode disposed on the shaft and having a continuous outer surface, wherein the electrode outer surface circumscribes the shaft along a length of the shaft and is eccentric in a radial cross-section.

20 33. The catheter according to claim 32, wherein the shaft longitudinal axis is a center longitudinal axis and the ablation electrode outer surface has a center longitudinal axis; and
the center longitudinal axis of the ablation electrode outer surface and the shaft center longitudinal axis are eccentric.

25 34. The catheter according to claim 33, wherein the ablation electrode outer surface has bipolar symmetry about only one axis in a radial cross-section.

35. The catheter according to claim 32, wherein the outer surface of the ablation electrode is stiff.

30 36. The catheter according to claim 32, wherein the ablation electrode has an outer surface constructed of a single piece of material.

AMENDED SHEET

- 21 -

37. The catheter according to claim 32, wherein the ablation electrode is rotatable around the shaft longitudinal axis.

38. The catheter according to claim 37, wherein the ablation electrode is
5 rotatable relative to the shaft.

39. The catheter according to claim 37, wherein the ablation electrode is rotatable together with the shaft.

10 40. The catheter according to claim 37, wherein the ablation electrode is constructed and arranged to change a distance between an outer surface of the shaft and a tissue surface when rotated around the shaft longitudinal axis.

15 41. The catheter according to claim 32, wherein the electrode outer surface is oval in a radial cross-section.

42. The catheter according to claim 32, wherein the electrode outer surface has a flat surface.

20 43. The catheter according to claim 32, in combination with an ablation energy supply, the energy ablation supply being electrically connected to the ablation electrode.

25 44. A catheter for ablating tissue, comprising:
a shaft for positioning an ablation electrode in contact with a tissue surface, the shaft having an outer surface that is eccentric in a cross-section;
an ablation electrode disposed on the shaft;
wherein, in a first shaft orientation, the shaft outer surface is positioned a first distance from the tissue surface in the vicinity of the ablation electrode, and in a
30 second, rotated shaft orientation, the shaft outer surface is positioned a second

distance from the tissue surface in the vicinity of the ablation electrode, the second distance being different than the first distance.

- 5 45. A catheter for ablating tissue, comprising:
 a shaft for positioning an ablation electrode at a distance from a tissue surface;
 an ablation electrode disposed on the shaft and having an outer surface;
 wherein the ablation electrode is moveable along the shaft in a longitudinal direction and the shaft is configured such that movement of the ablation electrode along the shaft in the longitudinal direction changes the distance between the electrode outer surface and the tissue surface.

- 15 46. The catheter according to claim 45, wherein the ablation electrode is a ring electrode.

47. The catheter according to claim 45, wherein the electrode outer surface is eccentric in a cross-section.

- 20 48. The catheter according to claim 45, wherein a longitudinal portion of the shaft is constructed and arranged to be spaced from the tissue surface.

49. A catheter for ablating tissue, comprising:
 a shaft for positioning an ablation electrode in contact with a tissue surface;
25 an ablation electrode disposed on the shaft and having an outer surface;
 wherein the ablation electrode is moveable along the shaft in a longitudinal direction and the shaft is configured such that movement of the ablation electrode along the shaft in the longitudinal direction positions the electrode surface at a distance from the tissue surface.

- 30 50. A catheter for ablating tissue, comprising:

- 23 -

a shaft for positioning an ablation electrode at a distance from a tissue surface; and

an ablation electrode rotatably disposed on the shaft and constructed and arranged to change a distance between an outer surface of the ablation electrode and the tissue surface when rotated relative to the shaft longitudinal axis.

51. The catheter according to claim 50, wherein the outer surface of the ablation electrode is eccentric in a cross-section.

10 52. The catheter according to claim 50, wherein the ablation electrode outer surface has a center axis that is eccentric with a center axis of the portion of the shaft on which the ablation electrode is disposed.

15 53. A method of changing a distance from an outer surface of a catheter shaft to a tissue surface, comprising:

(a) placing an ablation electrode into contact with a tissue surface using a catheter shaft such that an outer surface of the catheter shaft is disposed a distance from the tissue surface in the vicinity of the ablation electrode; and

20 (b) rotating the ablation electrode to change the distance from the outer surface of the catheter shaft to the tissue surface.

54. The method according to claim 53, wherein the ablation electrode is eccentrically mounted on the catheter shaft.

25 55. The method according to claim 53, wherein the ablation electrode has an outer surface that is eccentric in a cross-section.

56. The method according to claim 53, wherein the ablation electrode has a continuous outer surface.

30

- 24 -

57. The method according to claim 53, wherein the outer surface of the ablation electrode is stiff.

58. The method according to claim 53, wherein an outer surface the
5 ablation electrode is constructed of a single piece of material.

59. The method according to claim 53, wherein the ablation electrode is a ring electrode.

60. The method according to claim 53, wherein (b) comprises rotating the
10 catheter shaft.

61. The method according to claim 53, wherein (b) comprises rotating the
15 ablation electrode relative to the catheter shaft.

62. The method according to claim 53, wherein (b) comprises moving the
20 ablation electrode along the shaft to rotate the ablation electrode relative to the
catheter shaft.

63. The method according to claim 53, wherein the electrode is a ring
25 electrode.

64. A method of changing a distance from an ablation electrode to a tissue
surface, comprising:

25 (a) disposing an ablation electrode at a first distance from a tissue
surface using a catheter shaft having a longitudinal direction; and

(b) disposing the ablation electrode at a second distance, different than
the first distance, from the tissue surface by moving the ablation electrode along the
catheter shaft in the longitudinal direction.

30 65. The method according to claim 64, further comprising:

AMENDED SHEET

(c) rotating the ablation electrode to change the distance from the catheter shaft to the tissue surface.

5 66. The method according to claim 64, wherein the ablation electrode is a ring electrode.

10 67. A catheter for ablating tissue, comprising:
 a shaft for positioning an ablation ring electrode in contact with or near
 a tissue surface; and
 an ablation ring electrode disposed on the shaft; wherein
 a distance from the shaft near the ablation ring electrode to the tissue
 surface is adjustable; and
 the ablation ring electrode is rotatably disposed on the shaft and
 constructed and arranged to change the distance between the shaft near the ablation
15 ring electrode and the tissue surface when rotated around a shaft longitudinal axis.

3/4

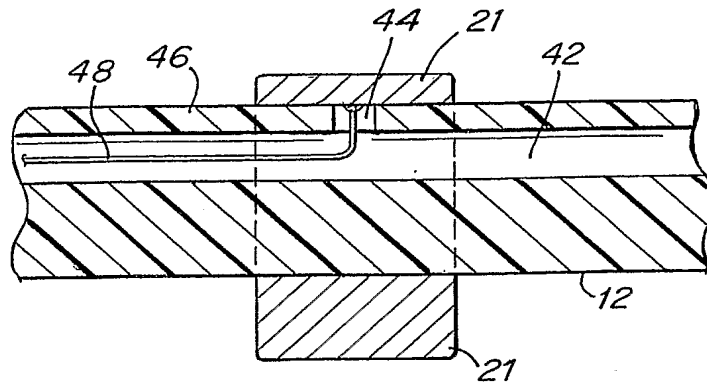


Fig. 10

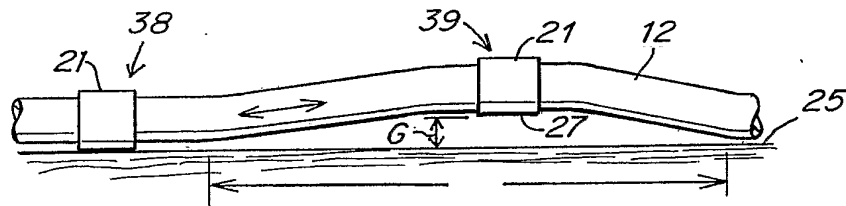


Fig. 11

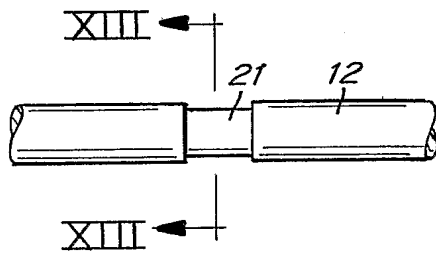


Fig. 12

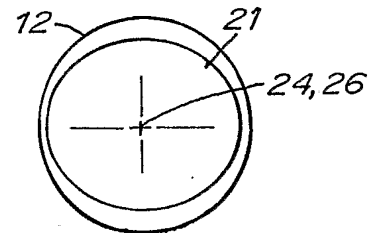


Fig. 13

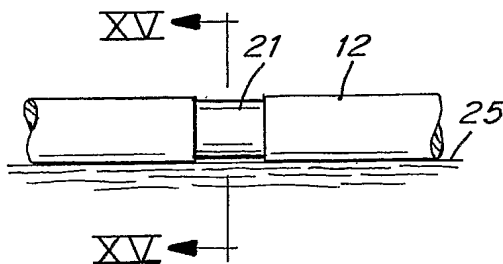


Fig. 14

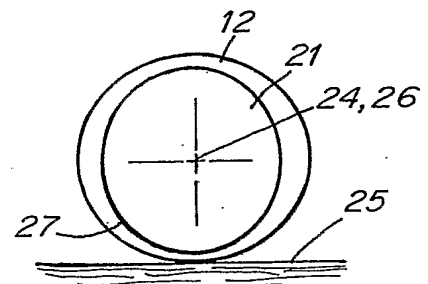


Fig. 15